DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#18

AUG - 3 1993

Re: TILADE®
Docket No. 93E-0090

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DEPUTY ASSISTANT COMMISSIONER FOR PATENTS

The Honorable Michael K. Kirk
Acting Assistant Secretary of Commerce and
Acting Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Kirk:

This is in regard to the application for patent term extension for U.S. Patent No. 4,474,787, filed by Fisons plc, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for TILADE®, the human drug product claimed by the patent.

The total length of the review period for TILADE® is 3495 days. Of this time, 1365 days occurred during the testing phase and 2130 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: June 8, 1983.

   The applicant claims March 6, 1983, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND was placed on clinical hold on March 4, 1983, and was removed from hold on June 8, 1983. Therefore, the IND effective date is June 8, 1983.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: March 3, 1987.

   The applicant claims February 27, 1987, as the date the new drug application(NDA)for TILADE® (NDA 19-660) was initially submitted. However, FDA records indicate that NDA 19-660 was initially submitted on March 3, 1987.

3. The date the application was approved: December 30, 1992.

   FDA has verified the applicant's claim that NDA 19-660 was approved on December 30, 1992.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

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